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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,663	01/03/2002	Mudit K. Jain	HRT-58192	1583

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EXAMINER

GIBSON, ROY DEAN

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 08/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/037,663	JAIN, MUDIT K.
Examiner	Art Unit	
Roy D. Gibson	3739	

-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 01 July 2002.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 34-44 is/are allowed.
- 6) Claim(s) 1-9, 17, 18, 20, 21 and 29-31 is/are rejected.
- 7) Claim(s) 10-16, 19, 22-28, 32 and 33 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2,3</u> .	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Specification fails to disclose how a pressure sensor is adapted to provide temperature data as recited in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 17-18, 20 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Fleischman et al. (6,241,724).

As to claim 1, Fleischman et al. disclose a catheter comprising: (refer to Figures 1, 5 and 19)

a shaft (20) having a distal segment adapted to be positioned in a biological organ, the distal portion having a tissue-contacting area; and at least one pressure sensor (224) associated with the distal segment and positioned within the tissue-contacting area to provide tissue pressure data indicative of the pressure exerted on the distal segment at or near the pressure sensor (col. 4, line 26-col. 6, line 31, col. 10, lines 14-37 and col. 13, lines 9-27).

As to claim 2, Fleischman et al. disclose the catheter further comprises an electrode system (26-29) adapted to transmit energy to the tissue (Figures 2-6 and col. 4, lines 42-64).

As to claim 3, Fleischman et al. disclose the electrode system comprises at least one electrode and the at least one pressure sensor (224) is located on the electrode (Figure 19 and col. 10, lines 14-26).

As to claims 17 and 18, Fleischman et al. disclose the catheter further comprises at least one temperature sensor (31) associated with the distal segment and positioned within the tissue-contacting area (col. 5, line 53-col. 6, line 31), and that the electrode system comprises at least one electrode and at least one temperature sensor (31) is located on the electrode (Figure 19 and col. 10, lines 7-13).

As to claim 20, Fleischman et al. disclose a system comprising:  
a generator for providing energy (RF generator # 23),  
a catheter and pressure sensor as detailed above; and

a processor (control system # 16) responsive to the pressure data and configured to analyze the pressure data to provide an indication of contact between the distal segment at or near the pressure sensor and the tissue (col. 4, lines 28-66 and col. 10, lines 14-26).

As to claim 29, Fleischman et al. disclose temperature sensor as detailed above (col. 5, line 53-col. 6, line 57).

Claims 1-2, 4, 20, 21, 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Ben-Haim (6,063,022).

As to claim 1, Ben-Haim discloses a catheter comprising:

a shaft (Figure 1) having a distal segment adapted to be positioned in a biological organ, the distal portion having a tissue-contacting area; and  
at least one pressure sensor (70) associated with the distal segment and positioned within the tissue-contacting area to provide tissue pressure data indicative of the pressure exerted on the distal segment at or near the pressure sensor (col. 3, lines 36-44, col. 4, lines 1-67 and col. 5, line 46-col. 6, line 46).

As to claim 2, Ben-Haim discloses the catheter further comprises an electrode system (72) adapted to transmit energy to the tissue (col. 6, lines 30-46).

As to claim 4, Ben-Haim discloses the electrode system comprises at least one electrode ~~6720~~ and the at least one pressure sensor (70) is located on the shaft adjacent the electrode (Figure 1).

As to claims 20 and 21, Ben-Haim discloses a system comprising:  
a generator for providing energy (RF generator),  
a catheter and pressure sensor as detailed above; and  
a processor (control system # 36) responsive to the pressure data and  
configured to analyze the pressure data to provide an indication of contact between the  
distal segment at or near the pressure sensor and the tissue by inherently comparing  
the pressure data to a reference value to determine the extent of the contact (col. 3,  
lines 36-56, col. 4, lines 28-34, col. 6, lines 30-67 and col. 8, lines 1-15).

As to claims 30 and 33, Ben-Haim disclose a system for assessing the adequacy  
of contact between an electrode (72) and tissue, the system comprising:

a pressure sensor located adjacent an electrode and processor as detailed  
above (col. 3, lines 36-56, col. 4, lines 28-34, col. 6, lines 30-67 and col. 8, lines 1-15).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all  
obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 5-8 rejected under 35 U.S.C. 103(a) as being unpatentable over  
Simpson et al. (6,049,737) in view of Fleiscman et al.

Simpson et al. disclose a catheter having a shaft (Figure 1, # 31) comprising a  
plurality of band electrodes (32) arranged in a linear array for treatment of biological

tissue (col. 2, lines 10-55 and col. 3, lines 1-33), but lacks at least one pressure sensor or a plurality of pressure sensors associated with each electrode adapted to provide pressure data indicative of the pressure exerted on the distal segment. However, Fleischman et al. disclose a pressure sensors located on each electrode associated with the distal segment as detailed above as an orientation means and a tissue contact means to provide data indicative of the pressure exerted on the distal segment (col. 10, lines 14-26). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Simpson et al., as taught by Fleischman et al., to provide additional or alternative equivalent means to detect the contact between the catheter distal segment and the tissue to be treated. Further to claims 7-8, the examiner maintains that it would have been obvious to a skillful artisan to located the pressure sensors on or near the electrodes or in the longitudinal center of the array of electrodes to monitor and control the application of RF energy to the treatment site.

***Allowable Subject Matter***

Claims 34-44 are allowed.

Claims 10-16, 19, 22-28 and 32-33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Goldin et al. (6,569,160) disclose a system and method for detecting electrode-tissue contact, but lacks a pressure sensor; Stockert (6,592,580) discloses an apparatus for the HF treatment of tissue including multiple electrodes with temperature sensors; and Woodruff et al. (6,287,297) disclose an energy delivery system and method, but also lack a pressure sensor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 703-308-3520. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 703-308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

  
Roy D. Gibson  
Primary Examiner  
Art Unit 3739

August 20, 2003